



**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q85654

Nicoletta BIANCHI, et al.

Appln. No.: 10/519,990

Group Art Unit: 1614

Confirmation No.: 3209

Examiner: Not Yet Assigned

Filed: January 04, 2005

For: A NOVEL USE OF RAPAMYCIN AND STRUCTURAL ANALOGUES THEREOF

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

**MAIL STOP AMENDMENT**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after

INFORMATION DISCLOSURE STATEMENT  
U.S. Appln. No.: 10/519,990

filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Respectfully submitted,



Robert V. Sloan  
Registration No. 22,775

Date: February ~~10~~<sub>13</sub>, 2006

Substitute for Form 1449 A & B/PTO		<b>INFORMATION DISCLOSURE E STATEMENT BY APPLICANT</b>		<i>Complete if Known</i>	
		(use as many sheets as necessary)		Application Number	10/519,990
				Confirmation Number	3209
				Filing Date	January 04, 2005
				First Named Inventor	Nicoletta BIANCHI
				Art Unit	1614
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	Q85654
Sheet	1	of			

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		
		US			
		US			

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		G. RODGERS et al., "Novel Treatment Options in the Severe $\beta$ -Globin Disorders", British Journal of Haematology, 91:263-268, 1995.	
		J. ROCHETTE et al. "Fetal Hemoglobin Levels in Adults", Blood Reviews, 8:213-224, 1994.	
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		DOVER et al., "Increased Fetal Hemoglobin in Patients Receiving Sodium 4-Phenylbutyrate", New England Journal of Medicine, 327:569-570, 1992.	
		IKUTA et al. "Cellular and Molecular Effects of a Pulse Butyrate Regimen and New Inducers of Globin Expression and Hematopoiesis" Annals of New York Academy of Sciences, 850: 87-99, 1998	
		KAHAN, "Sirolimus: a comprehensive review" Expert Opinion. 2001 Nov; 2(11): 1903-1917	
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		TRAUTMANN, et al. "Targeting keratinocyte apoptosis in the treatment of atopic dermatitis and allergic contact dermatitis". Journal of Allergy Clinical Immunology, November 2001 839-846	
		REITAMO et al. "Efficacy of Sirolimus (rapamycin) administered concomitantly with a sub therapeutic dose of cyclosporine in the treatment of severe psoriasis: a randomized controlled trial" British Journal of Dermatology, 2001: 145: 438-445.	
		GUBA et al. "Rapamycin inhibits primary and metastasis tumor growth by antiangiogenesis: involvement of vascular endothelial growth factor" National Medical February 2002, Vol. 8, No. 2, 128-135	
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		RADOVANCEVIC et al. "Rapamycin reduces rejection in heart transplant recipients" Transplantation Proceedings, Vol. 33, 3321-3222, 2001	
		NISHIDA et al. "Sirolimus (Rapamycin)-Based Rescue Treatment following chronic rejection after liver transplantation" Transplantation Proceedings, 33: 1495 (2001)	
		BIANCHI et al. "Induction of Erythroid Differentiation of Human K562 Cells by Cisplatin Analogs" Biochemical Pharmacology Vol. 60, 31-40, 2000	
		BIANCHI et al. "The DNA-binding drugs mithramycin and chromomycin are powerful inducers of erythroid differentiation of human K562 cells". British Journal of Haematology, 1999 104:258-265	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		FIBACH, "Techniques for Studying Stimulation of Fetal Hemoglobin Production in Human Erythroid Cultures", Hemoglobin, 22(5&^), 445-458, 1998	
		FIBACH et al. "Hydroxyurea Increases Fetal Hemoglobin in Cultured Erythroid Cells Derived From Normal Individuals and Patients with Sickle Cell Anemia or $\beta$ -Thalassemia" Blood, Vol. 81, No. 6 (March 15), 1993:1630-1963.	
		HEID et al. "Real Time Quantitative PCR", Genome Research, 6:986-994, 1996	
		GIBSON et al. "A Novel Method for Real Time Quantitative RT-PCR", Genome Research, 6:995-1001, 1996	

Examiner Signature		Date Considered	
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